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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,561	11/07/2001	Guo-Bin Wang	11113/9	3657

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EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,561	WANG ET AL.	
	Examiner	Art Unit	
	Christopher P. Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,32 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 21, 2006 has been entered.

EXAMINER'S NOTES

2. Claim 32 is non-compliant with 37 CFR 1.121, because the claim has been amended. Therefore, the identifier should be changed from "original" to "currently amended".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 31, 32 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 32, 35, and 36, the limitation "the surface of the substrate" lacks antecedent basis because it is not understood if this limitation is referring to a particular surface of the substrate. If the limitation is referring to a particular surface of the substrate, it is not understood to which surface "the surface" refers. For examination purposes the surface of the substrate is considered the luminal surface of the substrate.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United

States and was published under Article 21(2) of such treaty in the English language.

6. Claims 31, 32, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Fydelor et al (USPN 4,377,010).

Regarding claim 31, Fydelor et al anticipate a medical device (see abstract) comprising a substrate constructed and arranged for insertion into a patient and having at least one luminal surface such as a catheter (col.2, l.26-27). The medical device further comprises a plurality of monomer molecules directly graft polymerized onto the surface of the substrate, forming a coating thereon, from a medium having reversed phase properties from the substrate, in terms of hydrophilicity (see abstract and col.2, l.38-51). The coating comprises at least one salt (col.3, l.4-10). The graft polymerization is thermally initiated by an organic free radical initiator, which organic free radical initiator is on the surface of the substrate prior to thermal initiation (col.3, l.11-18). Furthermore, the limitation "thermally initiated" is a process limitation and receives little patentable weight in an article claim. Fydelor teaches the same materials being grafted together and the use of the same photoinitiators taught in the instant specification as organic free radical initiators used to

in the graft polymerization. Therefore, structurally Fydelor teaches all of the claimed limitations and the fact that the organic free radical initiator present is irradiated by UV or visible light rather than heat is not germane to the patentability of the product, because the same product can be formed by multiple methods, absent the showing of unexpected results. Fydelor teaches that the graft polymerization is present on the surface of the substrate and therefore the initiator must be on the surface. The limitations "prior to thermal initiation" and "at the time of thermal initiation" are process limitations and receive little patentable weight in an article claim. The presence of the organic free radical initiator on the surface of the substrate is a structural limitation, but the timing of when the initiator is placed on the surface is not germane to patentability of an article claim. Regarding claim 32, articles are defined by what the article is not what the article does. Merely stating that a catheter is a PTCA catheter, cardiology catheter, central venous catheters, urinary catheters, drain catheter, or dialysis catheter, is given little patentable weight because no structure is provided beyond that the medical device in the shape of a tube for forming a catheter. The medical device of Fydelor is a catheter used in living bodies so it meets the structural limitations of

claim 32. Regarding claim 34, the substrate has a lumen having both interior and exterior surfaces, since it is a catheter. At least a portion of both the interior and exterior of the lumen is coated with monomer molecules graft polymerized to the lumen surface, since the polymerization is on one or more of its surfaces (col.2, l.44-46). Regarding claim 35, Fydelor et al anticipate a system for forming a graft polymerized medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one luminal surface such as a catheter (see abstract and col.2, l.24-27). Fydelor et al further anticipate an organic free radical initiator capable of thermally initiating a graft polymerization reaction on the substrate to generate reactive radical sites on the surface of the substrate (see abstract and col.3, l.15-17). The catheter further comprises a composition comprising one or more monomers in a medium which has reversed properties to the substrate, in terms of hydrophilicity, and comprising at least one salt wherein the polymer graft polymerized is grafted directly onto the substrate and wherein the graft polymerization is thermally initiated by an organic free radical initiator on the surface of the substrate at the time of thermal initiation (see abstract and col.3, l.4-18 and rationale regarding claim 32). Regarding claim 36, Fydelor et al anticipate a medical

device comprising a substrate constructed and arranged for insertion into a patient (col.2, l.16-28). A coating is applied to the substrate free of a binding component or a linking component comprising a plurality of monomer molecules directly graft polymerized onto the surface of the substrate form a medium having reversed phase properties relative to the substrate in terms of hydrophilicity (see abstract and rationale regarding claim 32).

7. Claims 31, 32, and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal et al (USPN 6,287,285).

Regarding claims 31 and 35, Michal et al teach a medical device (see abstract) comprising a substrate constructed and arranged for insertion into a patient and having at least one luminal surface such as a catheter (see abstract) and a plurality of monomer molecules directly graft polymerized onto the surface of the substrate from a medium having reversed phase properties from the substrate, in terms of hydrophilicity (see abstract). In one embodiment, a hydrophilic compound is directly grafted onto a hydrophobic substrate (col.5, l.9-17). The medium comprises a salting agent such as potassium bromide or sodium chloride, which are potassium and sodium salts

respectively, which are considered salting agents as defined in the applicant's specification on Page 14 lines 4-8. The hydrophilic coating is also applied with an initiator or grafting component capable of initiating a graft polymerization reaction on the substrate, to generate reactive radical sites on the surface of the substrate (see abstract). Michal teaches that the initiation of the graft-polymerization is initiated photoinitiators, which are organic free radical initiators, and are irradiated with UV or visible light, which inherently will produce at least a slight thermal increase (col.11, l.11-15). Furthermore, the limitation "thermally initiated" is a process limitation and receives little patentable weight in an article claim. Michal teaches the same materials being grafted together and the use of the same photoinitiators taught in the instant specification as organic free radical initiators used to in the graft polymerization. Therefore, structurally Michal teaches all of the claimed limitations and the fact that the organic free radical initiator present is irradiated by UV or visible light rather than heat is not germane to the patentability of the product, because the same product can be formed by multiple methods, absent the showing of unexpected results. Michal teaches that the graft polymerization is present on the surface of the substrate and therefore the initiator must be on the

surface. The limitations "prior to thermal initiation" and "at the time of thermal initiation" are process limitations and receive little patentable weight in an article claim. The presence of the organic free radical initiator on the surface of the substrate is a structural limitation, but the timing of when the initiator is placed on the surface is not germane to patentability of an article claim. Regarding claim 32, the substrate is a guide wire or catheter such as a PTCA catheter (col.5, l.53-56). Regarding claim 34, the hydrophilic coating is added to all or part of the medical device including the interior and exterior surfaces (col.14, l.1-15). Regarding claim 36, Michal et al anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient (see abstract and col.1, l.10-14). The device further comprises a coating thereon, free of a binding component or a linking component, comprising a plurality of monomer molecules directly graft polymerized onto the surface of the substrate form a medium having reversed phase properties relative to the substrate in terms of hydrophilicity (col.5, l.9-17).

ANSWERS TO APPLICANT'S ARGUMENTS

8. Applicant's arguments regarding the 35 U.S.C. 102 rejections of claims 31, 32, 34, and 35 as anticipated by Fydelor have been fully considered but they are not persuasive.

In response to Applicant's argument that the there is not a showing of how Fydelor uses chemical initiators such as organic peroxides to arrive at applicant's invention, prior art is presumed to be operable/enabling. When the reference relied on expressly anticipates all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. See MPEP 2121. Fydelor expressly anticipates a medical device substrate having a graft polymerized coating on the surface, in which the coating has reversed phase properties from the substrate in terms of hydrophilicity and comprises at least one salt. Fydelor teaches that the initiation is preferably caused by ionizing radiations, but may also by initiated by heat and chemical initiators such as organic peroxides and other free radical initiators (col.3, l.11-17). Therefore, Fydelor teaches the structural components of graft polymerization by heat or thermal initiated organic free radical initiators. Thus, the burden is on the applicant to provide facts rebutting the presumption of operability of

Fydelor reference. The prior art reference is not required to provide how the structural components are used in order to anticipate the article.

9. Applicant's arguments regarding the 35 U.S.C. 102 rejections of claims 31, 32, 34, and 35 as anticipated by Michal have been fully considered but they are not persuasive.

In response to Applicant's argument that Michal cannot possible teach a device having at least one luminal surface that has the coating polymerized to it, the claims as currently presented do not require that the coating be present on the at least one luminal surface. The claims merely state that the device has at least one luminal surface and that the coating is applied on the surface of the substrate, but does not specify which surface of the substrate the coating is applied. Furthermore, Michal specifically teaches that the coating is polymerized to the inner surface of the catheter to facilitate displacement of objects, such as a guidewire, within a lumen of the catheter (col.14, l.10-13). In the same manner as presented above with regards to Fydelor, prior art is presumed to be operable/enabling. When the reference relied on expressly anticipates all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is

found, the burden is on applicant to provide facts rebutting the presumption of operability. See MPEP 2121.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB

CPB
April 10, 2006

ALICIA CHEVALIER
PRIMARY EXAMINER